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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,600	BEJANIN ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-54* is/are pending in the application.

4a) Of the above claim(s) *14-29 and 41-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/000489.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/29/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III in the reply filed on July 14, 2004 is acknowledged. The claims of Group III are limited to protein. In the Office action of June 17, 2004, claim 29, drawn to a polynucleotide, was inadvertently listed as a member of group III. However, this claim should have been listed with the claims of Group I (polynucleotides). Accordingly, claims 30-40 limited to proteins have been examined herein. Claims 14-29 and 41-54 are withdrawn from consideration as being drawn to a non-elected invention.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 30-40 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The claims as written do not sufficiently distinguish over proteins as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakbrabarty, 447 U.S. 303, 206 USPQ 193 (1980).*

To overcome this rejection it is suggested that the claims be amended to include purity limitations which would distinguish the claimed compounds, as enabled by the specification, over the naturally occurring compounds. For example, this rejection may be overcome by amendment of the claims to include the terminology "isolated and purified" and/or to provide a description of what the claimed products are "free of" relative to that of the natural source.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-35 and 38-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not appear to provide support for newly added claims 34-39. With respect to claims 34-36, the specification generally describes polypeptide fragments of SEQ ID NO: 4. The specification (page 385/Table III) also discloses the position of immunogenic epitopes in SEQ ID NO: 4 and teaches polypeptides comprising the C-terminal 31 amino acids of SEQ ID NO: 4 (i.e. "amino acids 237-267"; see page 129). However, the specification does not teach particular polypeptides that include amino acid L245 (claim 34), or amino acid V118 and L245

(claim 35). The disclosure of the concept of polypeptide fragments of varying lengths and the listing of a all possible lengths and amino acid residues that may be present within a polypeptide does not provide basis for specific polypeptides that consist of a fragment of SEQ ID NO: 4 that includes position L245 or positions L118 and L245.

With respect to claims 38-39, the specification (page 129) teaches that "The protein of SEQ ID NO:4 encodes a novel serine carboxypeptidase designated herein SCPhx." Thereby, the specification characterizes the polypeptide of SEQ ID NO: 4 and fragments thereof as having serine carboxypeptidase activity. However, the specification does not provide support for the broader concept that the polypeptide of SEQ ID NO: 4 has all types of carboxypeptidase activity and does not provide support for the concept that the polypeptide has the biological activity of inhibiting carboxypeptidase activity.

In the preliminary amendment filed April 29, 2002, Applicants state that support for the amendments to claims 30-40 can be found at pages 128-131 of the specification. However, for the reasons stated above, the teachings on pages 128-131 of the specification do not provide support for newly added claims 34-36 and 38-39.

5. Claims 37-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides consisting of "amino acids -26 to 267" of SEQ ID NO: 4 or consisting of "amino acids 1 to 267" of SEQ ID NO: 4, wherein said polypeptides have serine carboxypeptidase activity , does not reasonably provide enablement for polypeptides consisting of any fragment of SEQ ID NO: 4 wherein the polypeptides have the biological activity of carboxypeptidase activity or of inhibition of

carboxypeptidase activity . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands,* 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

The claims are drawn to polypeptide fragments of SEQ ID NO: 4 wherein the fragments have the biological activity of carboxypeptidase activity or inhibition of carboxypeptidase activity.

The specification (page 129) states that the SCPhx polypeptide of SEQ ID NO: 4 encodes for "a novel serine carboxypeptidase." The specification also teaches that amino acids –26 to –1 of SEQ ID NO: 4 constitute a signal sequence. Accordingly, the specification has enabled polypeptides consisting of "amino acids -26 to 267" of SEQ ID NO: 4 and consisting of "amino acids 1 to 267" of SEQ ID NO: 4, wherein said polypeptides have serine carboxypeptidase activity.

However, the specification does not exemplify any fragments of SEQ ID NO: 4 having other types of carboxypeptidase activity or having the ability to inhibit carboxypeptidase activity. Further, the specification does not exemplify any fragments other than amino acids 1 to 267 of SEQ ID NO: 4 having serine carboxypeptidase

activity. The specification does not provide any specific guidance as to which regions of SEQ ID NO: 4 are necessary to confer carboxypeptidase activity or the activity of inhibiting carboxypeptidase. There is no information provided in the specification as to the amino acids which make up the active site of the serine carboxypeptidase. There is also no information provided in the specification as to which amino acids of SEQ ID NO: 4 are critical to allow a polypeptide to act as an inhibitor of carboxypeptidase activity. Further, the specification does not teach which additional types of carboxypeptidase activity (e.g., cysteine-type carboxypeptidase, metallocarboxypeptidase, or glutamate carboxypeptidase activity, etc.) may be characteristic of fragments of SEQ ID NO: 4. The different types of carboxypeptidase have different biological substrates. However, there is no guidance provided in the specification as to what would be the substrate for the various fragments of SEQ ID NO: 4.

The claims read on fragments of SEQ ID NO: 4, from the dipeptide level up to one amino acid less than the full length polypeptide. This genus of polypeptide fragments is significantly large and it is highly unpredictable as to which fragments will have carboxypeptide activity.

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of

guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art. Further, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, the claims do not bear a reasonable correlation to the scope of enablement because the specification teaches only one fragment of SEQ ID NO: 4 (i.e., amino acids 1 to 267) which have serine carboxypeptidase activity. The specification does not teach any additional fragments of SEQ ID NO: 4 having serine carboxypeptidase activity and does not teach any fragments of SEQ ID NO: 4 having other types of carboxypeptidase activity or having the ability to inhibit carboxypeptidase activity. In the absence of specific guidance provided by the specification and in view of the unpredictability in the art, undue experimentation would be required to make and use the invention as it is broadly claimed.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31-39 are confusing and indefinite over the reference to particular amino acid positions in SEQ ID NO: 4. SEQ ID NO: 4 represents a polypeptide of 293 amino acids. Within the sequence listing, the amino acids are numbered from –26 to –1 to 1 to

267. However, the sequence listing also refers to a signal peptide sequence that spans amino acids "1...26." Accordingly, two different numbering schemes are used in SEQ ID NO: 4 – one in which the amino acids are numbered 1 to 293 (as is the standard for the numbering of amino acids in a sequence listing); and a second in which the amino acids are numbered –26 to –1 to 1 to 267. It is also noted that the "first" numbering scheme appears to be used in Table III, since amino acids at positions 270 and 277 to 287 of SEQ ID NO: 4 are referenced in this table. It is unclear as to which numbering scheme is being used in the claims and thereby it is unclear as to what is intended to be encompassed by "amino acids –26 to 267 of SEQ ID NO: 4" (claim 31), "amino acids 1 to 267 of SEQ ID NO: 4" (claims 32-33), "amino acid L245" (claim 34), "amino acid V118 and L245" (claim 35) and "amino acids 237 to 267" (claims 37-39).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31, 34, 35, 37 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Dumas (WO 99/53051).

Dumas teaches a polypeptide consisting of 51 amino acids wherein the polypeptide shares 100% identity with amino acids 1 to 51 (or –26 to +25) of present SEQ ID NO: 4 (see sequence comparison printout and page 437 of Dumas). Accordingly, Dumas teaches a polypeptide consisting of a fragment of SEQ ID NO: 1.

With respect to claims 34 and 35, the claims recite that the fragment comprises L245 or V118 and L245. The claims do not set forth the context of these amino acids – i.e., do not require any particular amino acids flanking these amino acids. Accordingly, these claims have been interpreted as including polypeptides which comprise a fragment of SEQ ID NO: 4 and which include a leucine or a leucine and a valine. The polypeptide of Dumas comprises both a leucine and a valine. Accordingly, the polypeptide of Dumas anticipates the claimed invention because this polypeptide spans a leucine and valine and consists of a fragment of SEQ ID NO: 4. With respect to claim 37, the polypeptide of Dumas has biological activity because Dumas (page 28) teaches that this polypeptide encodes for a signal sequence. Further, Dumas teaches that this polypeptide is useful for generating antibodies (page 109). With respect to claim 40, Dumas (page 109) teaches compositions comprising polypeptide and a pharmaceutically acceptable carrier and the use of the composition to inoculate animals for the purposes of generating antibodies.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Carla Myers
September 15, 2004

CARLA J. MYERS
PRIMARY EXAMINER